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Folic Acid and Carotid Intima-media Thickness: a 3-year randomised controlled trial (RCT) examining the effects of folic acid supplementation on vascular disease

Submission date 16/05/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 16/05/2005	**Overall study status** Completed	
Last Edited 23/05/2022	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)

NCT00110604

Protocol serial number
NTR23

Study information

Scientific Title
Folic Acid and Carotid Intima-media Thickness: a 3-year randomised controlled trial (RCT) examining the effects of folic acid supplementation on vascular disease

Acronym
FACIT

Study objectives
To determine if folic acid supplementation can slow down atherosclerotic progression, age-related cognitive decline and age-related hearing loss.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Randomised, double blind, placebo controlled, parallel group trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Vascular disease

Interventions
Three-year long daily (oral) supplementation with 0.8 mg folic acid versus placebo pill.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Folic acid

Primary outcome(s)

1. Change in mean carotid intima-media thickness
2. Change in maximum carotid intima-media thickness

Key secondary outcome(s))
1. Change in carotid distension
2. Change in hearing levels (pure tone air conduction averages of 0.5, 1, and 2 kHz & 4, 6 and 8 kHz)
3. Cognitive performance at year three (cognitive domains: simple speed, cognitive flexibility, and memory; and information processing speed and semantic memory)
4. Inflammatory markers and haemostasis markers

Completion date
01/12/2004

Eligibility

Key inclusion criteria
1. 50 - 70 years old
2. Men and post-menopuasal women
3. Vitamin B12 greater than or equal to 200 pmol/l
4. Homocysteine greater than or equal to 13 umol/l

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Key exclusion criteria
1. Current use of vitamin supplements containing B vitamins
2. Hormone replacement therapy or lipid-lowering therapy

Date of first enrolment
01/09/1999

Date of final enrolment
01/12/2004

Locations

Countries of recruitment
Netherlands

Study participating centre
Division of Human Nutrition
Wageningen
Netherlands
6700 EV

Sponsor information

Organisation
Wageningen Centre for Food Sciences (WCFS) (The Netherlands)

Funder(s)

Funder type
Research organisation

Funder Name
The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

Funder Name
Wageningen Centre for Food Sciences (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		02/01/2007		Yes	No
Results article		20/01/2007		Yes	No
Results article		01/05/2011	23/05/2022	Yes	No
Results article		01/06/2011	23/05/2022	Yes	No
Results article	post hoc analysis	06/04/2021	23/05/2022	Yes	No
	Study website				

Study website	11/11/2025	11/11/2025	No	Yes